REMARKS

Applicant respectfully requests reconsideration of the application in view of the following remarks.

I. Status of the Claims

Claim 1 is requested to be amended. Exemplary support for this amendment can be found on page 6 of the specification and in original claim 2. Claim 23 is requested to be added, to recite a specific embodiment described, for example, at page 8 of the application. Applicants respectfully request entry of this amendment after final because it does not require any additional search and consideration and, at the very least, places the application in better condition for appeal.

Claims 1-23 are pending and subject to examination on the merits.

II. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1 and 5 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The specific grounds of rejection are addressed below.

A. "Below Processing Temperatures"

The Office Action rejects claim 1 as allegedly indefinite for reciting "below processing temperatures." According to the Office Action, "the phrase renders the claim unclear because this processing temperature is not recited." Applicant respectfully traverses this rejection.

In assessing compliance with 35 U.S.C. § 112, second paragraph, the "essential inquiry . . . is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity." MPEP § 2173.02 (emphasis added). The claim language must not be considered in a vacuum. *Id.* Instead, the teachings of the prior art and the understanding of the skilled artisan must also be considered. *Id.*

Here, the claims define the claimed subject matter with a reasonable degree of clarity and particularity, and one of skill in the art readily would understand the metes and bounds of the recited "processing temperatures." As indicated in the specification, the "processing temperatures" are the temperatures at which the transdermal compositions are processed. *See* Specification, paragraph bridging pages 10-11. Those skilled in the art will know the processing temperatures being used for a given transdermal system and, therefore, can readily determine whether a given system is substantially free of liquids having a boiling point below such processing temperatures. Thus, the claims do not need to recite specific processing temperatures in order to satisfy §112.

The Office Action states that the claims are indefinite, because "the claims do not recite the specific materials used in the claimed invention" and that "using 'below processing temperature' or 'equal to or greater than the boiling points of the at least one low molecular weight drug' adds to indistinctness of the claim since Applicant compares to an unknown value which is not sufficient to compare to the prior art." Office Action at 7-8.

Claims need only describe the claimed invention with "a reasonable degree of clarity and particularity." Here, one of skill in the art would be able to readily determine the "processing temperature" based on the conditions being used, as discussed above. Thus, neither the specific materials nor the numerical value for a processing temperature need to be provided. Along those lines, Applicants respectfully point out that numerical values do not need to be provides to compare the claimed invention to the prior art. Depending on the polymers and drugs disclosed in the prior art, the "processing temperature" and the "boiling points of the at least one low molecular weight drug" are apparent or can readily be determined for comparison to the claimed invention.

Applicant therefore respectfully requests reconsideration and withdrawal of this rejection.

B. "Equal To Or Greater Than The Normal Boiling Points Of The At Least One Low Molecule Weight Drug"

The Office Action rejects claims 1 and 5 for reciting "equal to or greater than the normal boiling points of the at least one low molecule weight drug." According to the Office Action, "[t]he meaning is vague since the drug is not known; there is no way to compare its boiling point." Office Action at 3. Applicant respectfully traverses this ground of rejection.

The claims are clear and definite as written. The skilled artisan readily will understand the metes and bounds of the recitation that the transdermal system be substantially free of water and liquids having a boiling point equal to or greater than the normal boiling points of the at least one low molecular weight drug. For example, when formulating a transdermal system, the skilled artisan may select one or more low molecular weight drugs, at which point he or she will know (or readily could determine) the normal boiling point of the selected low molecular weight drug(s), and thus will know (or readily could determine) whether the transdermal system is substantially free of liquids having a boiling point equal to or greater than the normal boiling points of the selected low molecular weight drug(s). Thus, the claims do not need to recite specific drugs or their normal boiling points in order to satisfy §112.

As noted above, the Office Action states that the claims are indefinite because "the claims do not recite the specific materials used in the claimed invention." However, the specific materials do not need to be recited. Once the one or more low molecular weight drugs are selected, the skilled artisan would know or could determine whether the transdermal system is substantially free of liquids having a boiling point equal to or greater than the normal boiling points of the selected low molecular weight drug(s).

Applicant therefore respectfully requests reconsideration and withdrawal of this rejection.

III. Claim Rejections – 35 U.S.C. § 102

A. WO 93/00058 to Miranda *et al.*

Claims 1-6 and 10-21 stand rejected under 35 U.S.C. § 102 as allegedly anticipated by WO 93/00058 to Miranda *et al.* According to the Office Action, "Miranda teaches the shear resistance of 99 hours which is almost the same [as 100 hours] and also teaches that polyacrylate is preferably present in the pressure-sensitive adhesive composition in an amount ranging from about 2-96% by weight and the polysiloxane is present in an amount ranging from about 98-4%, and the composition according to Miranda comprises fillers, and excipients (page 6)." Office Action at 4. Applicant respectfully traverses this rejection.

Miranda does not anticipate the claimed invention because, for example, Miranda does not disclose a transdermal drug delivery system comprising a blend of (a) one or more polymers wherein at least one of said one or more polymers is a high shear resistant acrylic-based pressure-sensitive adhesive polymer and (b) a therapeutically effective amount of one or more drugs, at least one of which is a low molecular weight drug and liquid at or about room temperatures, as set forth in claim 1. Indeed, the Office Action fails to identify any particular polymer described in the '058 application that is a "high shear resistant acrylic-based pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit," let alone a teaching to use such a polymer in a transdermal system with a low molecular weight drug, as required by claim 1.

The Office Action argues that Miranda "does not have to describe the ingredients of the composition in the same words which Applicant uses." Office Action at 8. However, the differences between Miranda and the claimed invention are not merely ones of terminology. Miranda fails to disclose a system comprising a "high shear resistant acrylic-based pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit," as claimed.

Although the Office Action alleges that "Miranda teaches the shear resistance of 99 hours," that statement is not supported by any citation to the '058 application, and Applicant

could find no such teaching in the reference. Indeed, there is no teaching or suggestion in the '058 application of a transdermal system comprising a "high shear resistant acrylic-based pressure-sensitive adhesive polymer" and a low molecular weight drug that is liquid at or about room temperatures, as recited in the instant claims.

The '058 application discloses compositions which include acrylic-based polymers such as Duro-Tak 80-1194, Duro-Tak 80-11196, Duro-Tak 80-1197, Gelva 737, and Gelva 738. However, none of these acrylic based polymers has a shear resistance that is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit, as set forth in claims 19-21, or greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit as set forth in claims 1-18. Thus, the '058 application does not anticipate claims 1-21.

The Office Action contends that "since the prior art used the same polymers, the properties disclosed in the instant claims and not disclosed in the prior art are inherent." However, the Office Action fails to disclose which of the prior art polymers allegedly has "a shear resistance that is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit." Moreover, it is not enough that polymers having the recited shear resistance are known in the art. The polymers must be combined in a system, as claimed. The prior art, including Miranda, fails to disclose such a composition and the Office Action has not identified a single composition allegedly anticipating the claimed invention.

The Office Action also argues that "Applicant is contradicting his own disclosure" by arguing that Duro-Tak 80-1194, Duro-Tak 80-11196, Duro-Tak 80-1197, Gelva 737, and Gelva 738 do not have the recited shear resistance. More specifically, the Office Action states as follows: "Applicant used the same trademarks of polymers used by Miranda in his patent 6,316,022 and disclosed that the shear resistance of these polymers is .gtoreq. 50 hours at 4 pounds per square inch (psi) and 72.degree. Fahrenheit (.degree. F.), more preferably .gtoreq.100 hours at 4 psi and 72.degree. F., even more preferably .gtoreq.100 hours at 8 psi and 72° F." However, this is a misrepresentation of the '022 patent.

The '022 patent states that "[i]n a preferred embodiment" the high shear resistant polymers have a shear resistance which is greater than or equal to 50 hours at 4 pounds per

square inch and 72°F. The '022 patent at 60-65. The '022 patent also states that Duro-Tak 87-2852, Gelva Multipolymer Solution 737 and Duro-Tak 87-2194 are useful. However, the '022 patent does not state that each of those polymers are high shear resistant polymers with a shear resistance greater than or equal to 50 hours at 4 pounds per square inch and 72°F. Indeed, Gelva 737, the only polymer that overlaps with the '058 patent, is a moderate resistant polymer that does not have the recited shear resistance.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

B. EP 0 524 776 to Pfister *et al.*

Claims 1-5, 7, 8, 10, 12, and 14-21 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by EP 0 524 776 A1 to Pfister *et al.* According to the Office Action, "[a] blend of polymers are used in the invention [of EP '776] like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000 (page 5, lines 13+), nicotine-based drug, and co-solvent excipients (page 2, lines 13+)." Office Action at 5. Applicant respectfully traverses this rejection.

EP '776 does not anticipate the invention because, for example, EP '776 does not disclose a transdermal drug delivery system comprising a blend of (a) one or more polymers wherein at least one of said one or more polymers is a high shear resistant acrylic-based pressure-sensitive adhesive polymer and (b) a therapeutically effective amount of one or more drugs, at least one of which is a low molecular weight drug that is liquid at or about room temperatures, as set forth in claim 1. Instead, EP '776 generally relates to silicone-based pressure-sensitive adhesive polymer compositions. *See e.g.*, EP '776 at page 7, lines 33-57.

Claim 1 is distinguished over EP '776 because, for example, EP '776 does not disclose high shear resistance "acrylic-based pressure-sensitive adhesive polymer," as claimed. While EP '776 mentions the use of a "carbomer" in its silicone-based pressure sensitive adhesive, the "carbomer" is not a "high shear resistant acrylic-based pressure sensitive adhesive polymer," as recited in claim 1. *See* EP '776 at page 5, line 25-28.

Instead, the carbomer is used as a "cohesive strengthening agent" (*e.g.*, a filler) and is dispersed in the silicone pressure-sensitive adhesive to increase cohesive strength. *See* EP '776, page 5, lines 29-30. Thus the carbomer is not a "acrylic-based pressure-sensitive adhesive polymer," as claimed. The silicone polymer is the adhesive in the EP '776 composition. The carbomer is present only as a "cohesive strengthening agent."

Claims 1-21 are further distinguished over EP '776, because, for example, EP '776 does not suggest the use of the "carbomer" with "a low molecular weight drug with a molecular weight of less than about 300 daltons." Nothing in EP '776 suggests using a carbomer together with a "a low molecular weight drug with a molecular weight of less than about 300 daltons," as claimed.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

V. Claim Rejections – 35 U.S.C. § 103

Claims 1-22 stand rejected under 35 U.S.C. § 103 as allegedly anticipated by EP '776 in view of U.S. Patent No. 5,284,660 to Lee *et al.* In making this rejection, the Office Action cites EP '776 as the primary reference, and cites Lee for teaching a transdermal composition wherein the amount of the drug is 40% of the composition. Applicant traverses this rejection.

As discussed above, EP '776 does not teach or suggest the invention recited in the independent claims. Because Lee does not remedy this deficiency, the combination of EP '776 and Lee does not render the claimed invention obvious. Accordingly, this rejection is improper and should be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date June 29, 2007

By _____

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4094
Facsimile: (202) 672-5399

Courtenay C. Brinckerhoff
Attorney for Applicant
Registration No. 37,288